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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/926,322 | 10/15/2001 | Piero Del Soldato | 108907-00019 | 5288 |

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ARENT FOX KINTNER PLOTKIN & KAHN
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036

EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,322

Applicant(s)

DEL SOLDATO, PIERO

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. R, T₁, T_B, X₂, T_{BI}, T_C Y, etc., and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R-T₁- (wherein R is acetylsalicylic acid and variants thereof, for example, 5-aminoacetylsalicylic acid; T₁ is (CO)_t wherein t = 1); **B**_{bo} is absent, i.e., bo = 0; **C** is -T_C-Y- (wherein T_C is O and Y is formula III wherein Y³ is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

Group II. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R-T₁- (wherein R is carprofen and variants thereof, for example, etodolac; T₁ is (CO)_t wherein t = 1); **B**_{bo} is absent, i.e., bo = 0; **C** is -T_C-Y- (wherein T_C is O and Y is Y₀ wherein Y₀ is R'O and R' is linear or branched C₁₋₂₀) and s is 1 or 2.

Group III. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R-T₁- (wherein R is diclofenac sodium and variants thereof, i.e., benzeneacetic acid derivatives such as flurbiprofen and ibuprofen; T₁ is (CO)_t wherein t = 1); **B**_{bo} is absent,

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i.e., $bo = 0$; **C** is $-T_c-Y-$ (wherein T_c is O and Y is formula III wherein Y^3 is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

Group IV. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R- T_1- (wherein R is diflunisal and variants thereof, i.e., biphenyl-carboxylic acid derivatives; T_1 is $(CO)_t$ wherein $t = 1$); **B_{bo}** is absent, i.e., $bo = 0$; **C** is $-T_c-Y-$ (wherein T_c is O and Y is formula III wherein Y^3 is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

Group V. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R- T_1- (wherein R is flufenamic acid and variants thereof, i.e., benzoic acid derivatives; T_1 is $(CO)_t$ wherein $t = 1$); **B_{bo}** is absent, i.e., $bo = 0$; **C** is $-T_c-Y-$ (wherein T_c is O and Y is formula III wherein Y^3 is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

Group VI. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R- T_1- (wherein R is flunixin and variants thereof, i.e., pyridinecarboxylic acid derivatives; T_1 is $(CO)_t$ wherein $t = 1$); **B_{bo}** is absent, i.e., $bo = 0$; **C** is $-T_c-Y-$ (wherein T_c is O and Y is formula III wherein Y^3 is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

Group VII. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R- T_1- (wherein R is indomethacin and variants thereof; T_1 is $(CO)_t$ wherein $t = 1$); **B_{bo}** is absent, i.e., $bo = 0$; **C** is $-T_c-Y-$ (wherein T_c is O and Y is formula III wherein Y^3 is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

Group VIII. Claims 1-10 (in part), drawn to products of formula (I) wherein **A** is R- T_1- (wherein R is lornoxicam and variants thereof; T_1 is $(CO)_t$ wherein $t = 1$); **B_{bo}** is

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absent, i.e., $bo = 0$; **C** is $-T_c-Y-$ (wherein T_c is O and Y is formula III wherein Y^3 is a nitrogen containing heterocyclic ring system) and s is 1 or 2.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhausted as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and the examiner will endeavor to group the same.

3. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a $-N(O)$ group which does not define a contribution over the prior art. The substituents on the structure vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

4. Additionally, the vastness of the claimed subject matter and the complication in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

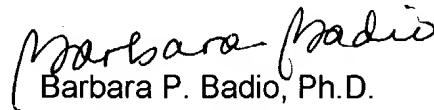
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Telephone Inquiry

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
September 29, 2004